

Protocol for implementing penicillin allergy de-labelling in adult patients in acute hospitals

Background

Approximately 10% of hospitalised patients are labelled as penicillin allergic, making tackling inappropriate penicillin allergy labelling a key antimicrobial stewardship initiative. Most people with a penicillin allergy label have not had an allergic reaction but instead have experienced an adverse reaction eg gastric upset. These reactions might have happened a long time ago, making the details difficult to remember.

People with a documented penicillin allergy are given alternative antibiotics to penicillin that aren't always as effective as the first-choice penicillin option would be, and this can mean poorer outcomes. Using alternative antibiotics instead of penicillins also increases the risk of getting other infections such as *Clostridioides difficile*. People also have an increased risk of antimicrobial resistant infections, longer hospital stay and other adverse events. It is important that only people who have a true allergy to penicillin have a penicillin allergy label on their medical record.

Removing the penicillin allergy label from medical records for those without a true penicillin allergy can reduce prescribing of broad-spectrum antibiotics which have higher resistance or ecotoxicity potential. This supports more sustainable antibiotic use, reduces the release of these drugs into the environment and promotes the wider One Health agenda.

It is therefore beneficial to assess whether patients have experienced a true allergic reaction. If patients have other types of adverse reaction or have an unclear history of penicillin allergy, then consider removing the penicillin allergy label.

Implementation of the penicillin allergy de-labelling (PADL) process within hospitals

Antimicrobial Management Teams (AMTs) should work closely with key clinical colleagues and within the governance structures of their boards. This is to ensure the safe and appropriate implementation and governance of the process.

Local lead(s) for process

It is important to identify a local clinical lead in each hospital to oversee the process. The local lead should work in collaboration with the board AMT and clinical teams. Penicillin allergy de-labelling assessment can be carried out in a range of wards, as agreed with local specialists, including respiratory and infectious diseases wards, pre-operative assessment clinics and out-patient antimicrobial therapy (OPAT) settings.

Local governance requirements

Local governance systems must be included within plans to implement the process and be content with the protocol and associated documentation. We suggest discussing with the Medical Director, Area Drug and Therapeutics Committee, local safety or risk committee and any other groups or individuals you feel should be informed. This may vary by board. If there are any concerns locally, please let us know and we will try to address these.

Patient inclusion and exclusion criteria

Clinicians should use the PADL algorithm to screen patients to determine whether they are suitable for de-labelling. This will involve a full assessment of the history of the patient's previous reaction to penicillin and assessing the patient's current risk of penicillin allergy. This may require contacting the patient's GP.

In addition to the patient exclusion criteria stated in the PADL algorithm, clinicians should exclude the following patients from the algorithm-based assessment:

- any patients who are deemed as acutely unwell and particularly if haemodynamically unstable
- patients currently requiring antibiotic treatment for a severe infection
- patients who are unable to participate in the assessment process or provide written consent for oral challenge, where oral challenge is being considered.

Undertaking a PADL assessment

- Take patient's full penicillin allergy history.
- Use PADL algorithm to clinically assess risk of penicillin allergy.
- Categorise patients into low risk, medium risk or high risk for penicillin allergy.

The PADL algorithm supports three possible outcomes following assessment:

- direct de-labelling based on clinical history assessment
- oral penicillin challenge
- retention of the penicillin allergy label based on clinical history assessment.

Risk categorisation

1. Patients assessed as low risk using the PADL algorithm

Low risk patients have a history that is inconsistent with penicillin allergy. They do not require oral challenge and may be de-labelled based on clinical history alone.

The patients with the following can be de-labelled directly without penicillin oral challenge:

- symptoms typical of intolerance rather than allergic reactions, including minor gastrointestinal upset, nausea, headache, fatigue
- family history of penicillin allergy but with no personal history of penicillin allergy
- history of tolerating penicillin following the initial reaction.

If a patient is directly de-labelled following assessment, medical staff should:

- update hospital electronic records and case notes to remove penicillin from the patient's allergy record
- document the basis for de-labelling
- send a standard GP letter advising that the penicillin allergy label has been removed and requesting removal of the allergy label from GP records
- give patients written information explaining the assessment outcome.

2. Patients assessed as medium risk using the PADL algorithm

Medium risk patients have a history that is unclear. Some assessed as medium risk following the algorithm may have history inconsistent with penicillin allergy but may not want to accept the removal of penicillin allergy label based on clinical history alone. For both groups of patients, the risk of penicillin allergy is low even if their recollection is unclear since they were not hospitalised for the reaction and their reaction is therefore not suggestive of a type 1 hypersensitivity reaction. Consider oral penicillin challenge.

Procedure for oral penicillin challenge in suitable patients

- Give patient the oral penicillin challenge information leaflet which contains information about the test and what will happen afterwards.
- Ask patients to give written consent for the test as part of discussion with the clinical team.
- Carry out the oral penicillin challenge using the protocol for administering oral challenge.
- Document details of the test including starting and finishing time and result in the medical notes.
- Give the patient written information about the result of their test.

Communication of test result

Once the test is complete discuss the result of the oral challenge and give them written information. The written information either confirms that they have been assessed as not having a penicillin allergy following oral penicillin challenge and can be de-labelled, or that they experienced a reaction and are confirmed as having a penicillin allergy.

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August 2026 | For review August 2029.

If a patient is confirmed as not allergic following an oral challenge, medical staff should:

- update hospital electronic records and case notes to remove penicillin from the patient's 'Allergies' fields
- send a standard letter to the patient's GP Practice advising of the assessment result and the need to remove their penicillin allergy label from GP records
- give the patient their discharge letter to facilitate updating allergy status in GP records.

If a patient is confirmed as allergic following an oral challenge, medical staff should:

- as soon as possible and on the same day of the test, ensure penicillin remains in the 'Allergies' field and make a note of the reaction
- send a standard letter to the patient's GP Practice advising of the assessment and the reaction following the oral challenge
- give patient their discharge letter to facilitate updating allergy status in GP records.

3. Patients assessed as high risk using the PADL algorithm

High risk patients should not undergo PADL and should retain their penicillin allergy label.

Patients are at high risk if they have a history of the following reactions after receiving penicillin:

- severe cutaneous adverse reactions, eg blistering rash, rash associated with severe systemic illness, history of oral or genital ulceration or blistering after using penicillin
- type 1 hypersensitivity reaction, eg collapse, face, throat swelling, breathing difficulty and itchy rash

Or, if they:

- are uncertain of their history of type 1 hypersensitivity reaction but report one or more of these reactions to penicillin:
 - occurred in the last 5 years
 - resulted in hospital admission or required urgent medical
 - definitely occurred within an hour of receiving penicillin.

Documentation and communication

For all patients undergoing PADL assessment:

- record assessment outcome in the clinical record
- document the basis for de-labelling or retention of the allergy label
- give patients written information explaining their assessment outcome
- inform GP practices about assessment outcome using the standardised correspondence templates.

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SAPG encourages feedback from clinical teams about any aspect of the process and invites suggestions for improvements. This can be done via email to his.sapg@nhs.scot.

Appendix: Resources available to support PADL in adult patients in acute hospitals as per algorithm assessment outcome

Resources available for de-labelling low risk patients

- PADL algorithm.
- Frequently asked questions for clinicians completing PADL.
- Penicillin allergy information sheet.
- Patient post-assessment information: No penicillin allergy.
- GP post-assessment letter: No penicillin allergy.

Resources available for de-labelling medium risk patients

- PADL algorithm.
- Frequently asked questions for clinicians completing PADL.
- Penicillin allergy information sheet.
- Protocol for administering an oral penicillin challenge.
- Oral penicillin challenge information leaflet.
- Pre-test patient consent form for oral challenge.
- Managing patients experiencing allergic symptoms during the oral challenge.
- Patient post-challenge information: No penicillin allergy.
- Patient post-challenge information: Penicillin allergy confirmed.
- Penicillin allergy card (only for patients with penicillin allergy confirmed).
- Standard letters to GPs to communicate penicillin challenge results and actions required.

Resources available for patients assessed as high risk using the PADL algorithm

- PADL algorithm.
- Frequently asked questions for clinicians completing PADL.
- Penicillin allergy information sheet.
- Patient post-assessment information: High risk of penicillin allergy.
- Penicillin allergy card.